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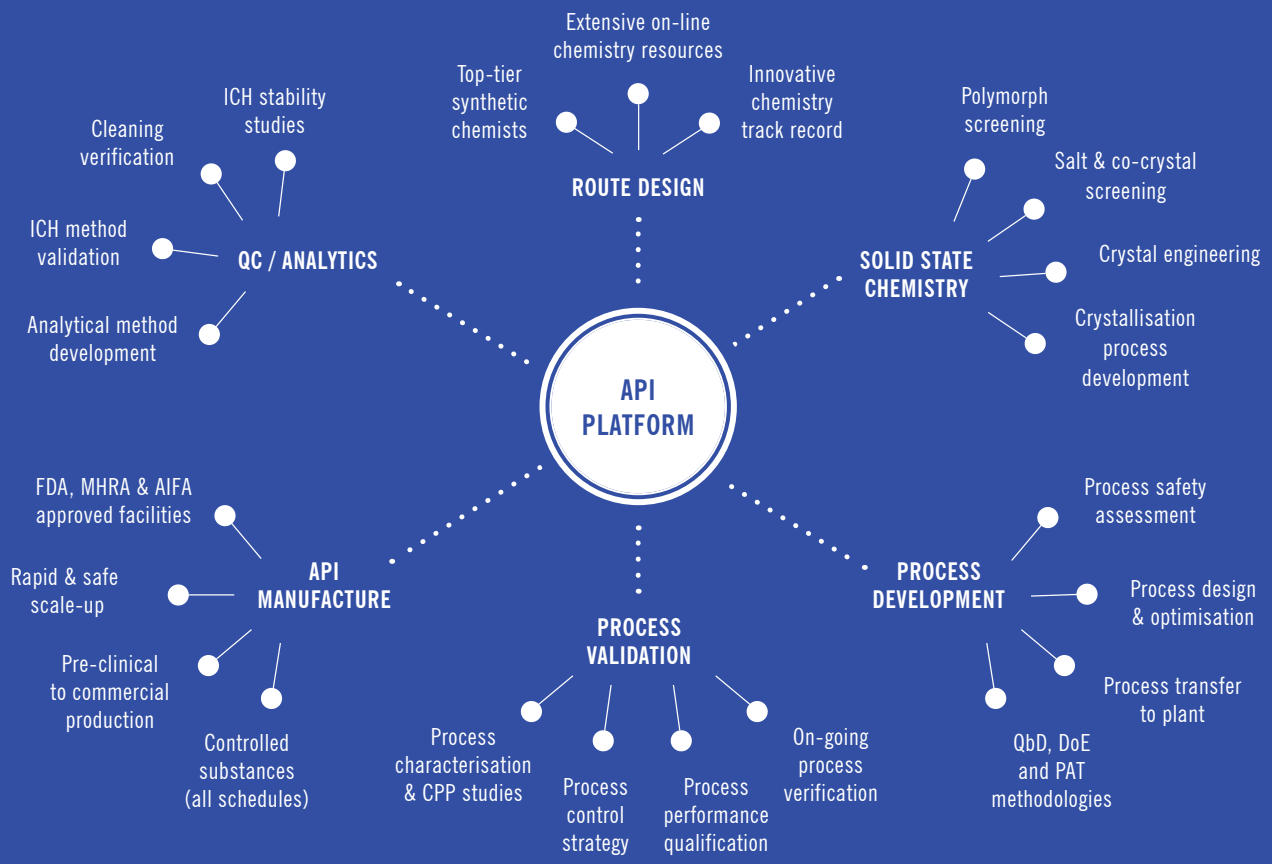
API CHEMICAL DEVELOPMENT AND MANUFACTURING

- Depth and breadth of scientific expertise, tools and methodologies enabling the delivery of industry-leading API route design and process development services
- Integrated Solid State Chemistry platform focused on delivering process robustness and control over intermediates and API solid form isolation
- Proven track record of non-GMP and GMP API manufacturing projects delivery from pre-clinical to commercial
- API Operations fully embedded within an integrated Global Drug Development platform with a strong track record of Pharma Industry programs delivery



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Evotec offers its partners high quality API Chemical Development & Manufacturing services embedded within a fully integrated Drug Discovery & Development platform

ROUTE DESIGN & SELECTION

Our teams of top-tier synthetic chemists leverage their creativity and access to an extensive suite of on-line chemistry resources to deliver innovative chemistry solutions. We pride ourselves in delivering safe, efficient, sustainable, cost-effective and patentable synthetic processes to our clients.

GENOTOXIC IMPURITIES

We offer industry-leading capabilities in performing risk assessments and designing control strategies for mutagenic impurities with a carcinogenic potential in compliance with the current ICH M7 guideline.

SOLID STATE CHEMISTRY

Our teams of Solid State Chemistry experts are fully integrated within our Chemical Development and Plant Chemistry teams and benefit from the support of Physical Properties specialists with experience in both API and DP projects. They rely on state-of-the-art automated equipment (Crystal 16, EasyMax) and PAT tools (FBRM, Raman) to conduct extensive polymorph, salt and co-crystal screens, and design superior crystal engineering strategies and crystallisation processes.

PROCESS DEVELOPMENT

Our experienced Process Development teams can handle complex syntheses, hazardous chemical transformations and controlled substances. They use DoE and PAT methodologies to build quality into processes. Working in close collaboration with our dedicated Process Transfer specialists, they have become experts at designing and optimising safe processes that can be rapidly and successfully transferred to our GMP Labs and Pilot Plants.

PROCESS VALIDATION

Our Chemical Development and Plant Chemistry teams have built a strong track record in validation of chemical processes for API commercial manufacturing. Using QbD, DoE and PAT methodologies they are experienced in performing process characterisation and CPP studies, defining process control strategies, designing and executing process performance qualification (PPQ) and on-going process verification (OGPV) protocols.

API MANUFACTURE

Our FDA, MHRA & AIFA approved GMP Labs and Pilot Plants offer the flexibility to manufacture a wide range of APIs (including potent and controlled substances) at various scales (volumes ranging from 20L to 1,600L). Our production teams have extensive experience in successfully delivering pre-clinical, clinical and commercial stages API manufacturing projects.

QC / ANALYTICS

Our API services include capabilities in analytical method development, ICH method validation, cleaning verification, ICH stability and forced degradation studies. We offer a comprehensive suite of modern analytical techniques, including instrumentation for the analysis of non-chromophoric species (CAD, ELSD, MS detection).

SUPPLY CHAIN / LOGISTICS

Our clients benefit from the strong relationships we have built with Raw Materials suppliers and custom manufacturers. Using our audited QA approved couriers our IATA qualified logistics experts ensure that the products we manufacture are delivered safely and diligently.

INTEGRATED DRUG DEVELOPMENT

Our API teams possess a pharmaceutical development mindset that sets us apart in the CDMO industry and underpins our unique fast integrated Drug Development service offering (INDiGO).